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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/347,175	07/01/1999	JAMES M. HOGLE	HU98-02PA	3518

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EXAMINER

ZEMAN, ROBERT A

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 12/04/2002

22

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/347,175

**Applicant(s)**

HOGLE ET AL.

**Examiner**

Robert A. Zeman

**Art Unit**

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-58 is/are pending in the application.
- 4a) Of the above claim(s) 11-15,22-40 and 46-57 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,2,4-6 and 58 is/are allowed.
- 6) ☒ Claim(s) 7-10,16-21 and 41-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1,2 and 4-58 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☒ Interview Summary (PTO-413) Paper No(s). 21.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_. 6) ☐ Other: \_\_\_\_\_.

Art Unit: 1645

### **DETAILED ACTION**

The request for reconsideration and request to withdrawn finality filed on 10-18-2002 is acknowledged. Applicant's Petition under 37 C.F.R. 1.144 has been fully considered and granted. Consequently, pursuant to said petition Groups I, II and XXI-XLVIII have been rejoined and the finality of the previous Office Action has been withdrawn. Claims 1-2 and 4-58 are pending. Claims 11-15, 22-40 and 46-57 remain withdrawn from consideration. Claims 1-2, 4-10, 16-21 and 41-45 are currently under examination.

#### ***New Claim Objections***

Claim 1 is objected to because of the following informalities: said claim contains an obvious typographical error. "moleculeconsisting" should read, "molecule consisting".

Appropriate correction is required.

Claims 16, 20-21, 42 and 44 are objected to for starting with the incorrect article. Independent claims should start with the article "The". Dependent claims should start with the article "A" or "An".

Appropriate correction is required.

#### ***New Claim Rejections***

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17-19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether undue experimentation is required are summarized *In re Wands* 858 F.2d 731, 8 USPQ 2<sup>nd</sup> 1400 (Fed. Cir. 1988). The court in *Wands* states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is "undue", not "experimentation" (*Wands*, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (*Wands*, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7), the predictability or unpredictability of the art, and (8) the breadth of the claims. While all these factors are considered, those used in determining the lack of enablement are discussed below.

The aforementioned claims all recite the limitation "derivative" with regard to various HdAg polypeptides. As written, this term is excessively broad since Applicant fails to adequately define said term in the specification. The specification is equally silent on what

Art Unit: 1645

methodologies are to be employed to create said “derivatives”. The specification merely states that they may be used. As such, the quantity of experimentation necessary would be extreme due to the lack of guidance provided by Applicant. Consequently, it would be impossible for one of skill in the art to predict what would fall under the category of “derivative” and equally impossible to predict what methodologies would be required to make said “derivative”.

Claims 7-10, 17, 19 and 44 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The rejected claims are drawn to “coiled-coil oligomers” and a method of using said oligomers. Said oligomers comprise at least two fusion molecules wherein said fusion molecules comprise a peptide consisting of amino acids 12-88 of the hepatitis D antigen (HDAg) or a fragment thereof that forms a coil and at least one binding moiety. The specification discloses that said binding moieties can be cytokines, interferons, interleukins, T cell receptors, Fc receptors, plasminogen activators, MHC, tumor suppressor genes, monoclonal antibodies, fragments of antibodies, drug resistance genes and ion channels (among others). The specification also discloses that the coiled-coil sequence is located in the N-terminal third (amino acids 12-60) of the HDAg molecule and that residues 50-60 of said molecule are important in oligomer formation. Finally, the specification discloses that HDAg coiled-coil monomers form octamers. However, the specification is silent on what binding moieties, if any could be fused to said monomers and maintain a coiled-coil conformation. The specification is equally silent on what binding moieties, if any, would allow for octamer formation. Additionally, the specification

Art Unit: 1645

gives no guidance on the techniques to be employed in “binding” said moieties to the HDAg or where on the HDAg molecule said moieties are attached. Consequently, given the lack of guidance and the lack of working examples within the specification, it would be impossible for one skilled in the art to make and/or use the claimed invention without undue experimentation.

Claims 41-45 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Said claims are drawn to methods of enhancing interaction between binding partners comprising contacting HDAg fusion molecules with a second binding moieties. The specification is silent on what steps are to be employed in the claimed methods. Furthermore, the specification fails to define what constitutes the “interaction” or what possible binding-partners would have an enhancing effect on said “interaction”. Consequently, due to the lack of guidance and working examples within the specification, it would be impossible for one skilled in the art to make and/or use the claimed invention without undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7-10, 16-21 and 41-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1645

Claims 7-10, 17, 19 and 44 are rendered vague and indefinite by the use of the term “coiled coil”. It is unclear what is meant by said term. Is said term meant to describe a conformational limitation of the oligomer or merely the HdAg portion of said oligomer? As written it is impossible to determine the metes and bounds of the claimed invention.

Claims 16 and 20-21 recite non-elected claims. Consequently, it is impossible to determine the metes and bounds of the claimed invention.

Claim 17 is rendered vague and indefinite by the use of the term “depicted”. It is unclear how a sequence is depicted. It is suggested that the claim be amended to read, “having an amino acid sequence selected from the group consisting of SEQ ID NOS...”.

Claim 17 recites improper Markush language. Said Markush group contains the term “and” as well as the term “or”. Proper Markush language requires that the ultimate term of the listed group be preceded by the term “and” when the preamble “selected from the group consisting of” is used.

Claims 17-19 are rendered vague and indefinite by the use of the term “derivative”. Applicant fails to define what is meant by “derivative”. Applicant fails to disclose what percentage of the protein must be present in order for a polypeptide to be considered to be a derivative or what processes must be utilized to generate said “derivatives”. Additionally, it is unclear what biochemical/immunological/physical properties must be present in order for a polypeptide to be considered a derivative. Consequently, it would be impossible to determine the metes and bounds of the claimed invention.

Claims 41 and 43 are rendered vague and indefinite by the use of the term “interaction”. It is unclear what is meant by said term. Is Applicant referring to binding or some other process?

Art Unit: 1645

✓ Claim 41 is rendered vague and indefinite by its failure to recite active method steps. The preamble of the claim states that the goal of said method is to “enhance the interaction between binding partners”. The only “step” recited is contacting binding partners. There are no steps recited that would lead to “enhanced interaction”.

Claim 42 is rendered vague and indefinite by the use of the term “presents”. It is unclear what is meant by said term. How are the said binding moieties “presented”?

✓ Claim 43 recites the limitation "ligands" in line 1. There is insufficient antecedent basis for this limitation in the claim.

✓ Claim 43 is rendered vague and indefinite by the term “on surfaces”. What surfaces is Applicant referring to? Cell surfaces? Container surfaces? As written, it is impossible to determine the metes and bounds of the claimed invention.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Lemon et al. (WO 96/20953).

Lemon et al. disclose HDAg peptides comprising SEQ ID NOS: 1, 3, 7-9 and 18-20 of the instant invention (see pages 31-41). Lemon et al. further disclose HDAg peptides wherein

Art Unit: 1645

serine residues within the HDAG peptides are replaced with cysteine residues (see page 8 and Table 1). Hence, Lemon et al. anticipate all the limitations of the instant claims.

Claims 17 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Houghton et al. (EP 0 251 757).

Houghton et al. disclose HDAG peptides comprising SEQ ID NOS: 12 and 17 of the instant invention (see Figures 1-3). Hence, Houghton et al. anticipate all the limitations of the instant claims.

Claim 17 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Makino et al. (Nature, Vol. 329, pages 343-346, 1987 – IDS-5).

Makino et al. disclose HDAG peptides comprising SEQ ID NOS: 8, 11, 13-16, 18-19, 23 and 25 of the instant invention (see page 345). Hence, Makino et al. anticipate all the limitations of the instant claims.

Claim 17 and 19 are rejected under 35 U.S.C. 102(a) as being anticipated by Dingle et al. (Journal of Virology, Vol. 72 No. 6, pages 4783-4788, 1998 – IDS-5).

Dingle et al. disclose HDAG peptides comprising SEQ ID NOS: 10 and 21 of the instant invention (see page 4784). Hence, Dingle et al. anticipate all the limitations of the instant claims.

Claim 17 - 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Imazeki et al. (Journal of Virology, Vol. 64, No. 11, pages 5594-5599).

Art Unit: 1645

Imazeki et al. disclose HDAG peptides comprising SEQ ID NOS: 5-7 of the instant invention (see page 5598). Imazeki et al. further disclose HDAG peptides wherein serine residues within the HDAG peptides are replaced with cysteine residues (see page 5598). Hence, Imazeki et al. anticipate all the limitations of the instant claims.

### ***Conclusion***

Claims 1-2, 4-6 and 58 are allowed.

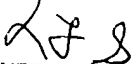
Claims 7-10, 16-21 and 41-45 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (703) 608-7991. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Robert A. Zeman  
December 2, 2002

  
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